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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,077	09/26/2006	Michael J. Delwiche	023070-139620US	8461
20350 7590 12/24/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				
EXAMINER				
TUNG, JOYCE				
ART UNIT		PAPER NUMBER		
1637				
MAIL DATE		DELIVERY MODE		
12/24/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/566,077

**Applicant(s)**

DELWICHE ET AL.

**Examiner**

Joyce Tung

**Art Unit**

1637

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 11, 12, 14 and 16-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-12, 14, 16-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The response filed 10/566,077 to the Office action has been entered. Claims 1-9, 11-12, 14, 16-23 are pending.

1. The rejection of claims 1-9 and 11 under 35 U.S.C. 112, second paragraph is withdrawn because of the amendment.
2. The rejection of claims 1-23 under 35 U.S.C. 102(b) as being anticipated by Alatosava et al. (5,849,488, issued Dec. 15, 1998) is withdrawn because of the amendment.
3. Applicant's arguments with respect to claims 1-9, 11-12, 14 and 16-23 have been considered but are moot in view of the new ground(s) of rejection.

### **NEW GROUNDS OF REJECTION NECESSITATED BY THE AMENDMENT**

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9, 11-12, 14, 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alatosava et al. (5,849,488, issued Dec. 15, 1998).

Alatosava et al. disclose a method of mastitis diagnosis by measuring the presence of specific DNA sequences in a milk sample (See column 3, lines 31-39). DNA is isolated from a milk sample from a female mammalian suspected to suffer from mastitis. The mammalian can be any species. Preferably it is a cow (See column 4, lines 16-19). The milk sample is contacted

with a metal ion chelator, EDTA (See column 10, lines 4-9), and then contacted with a detergent, Tween-20 (See column 10, lines 11-14). A PCR reaction is carried out (See column 10, lines 16-20). The PCR products are analyzed by sequencing (See column 8, lines 17-26). The presence of the target sequences can be determined by hybridization of a probe (See column 4, lines 43-60). The PCR products are also measured quantitatively with a fluorometric system (See column 7, lines 3-7). The milk sample is used with a pH 8 buffer (See column 10, lines 6-10).

Alatossava et al. also disclose inflammation study from mastitis milk in which the level of somatic cells in milk is estimated (See column 10, lines 35-36). A milk sample is lysed by heating and no protease is added to the milk sample (See column 10, lines 37-40). The DNA in the lysate is amplified by PCR. The amount of DNA in the PCR products is quantified by a densitometer. For comparison, the same milk sample is analyzed by two conventional somatic cell counting (SCC) tests. The results from a comparison study demonstrate that the DNA-based SCC determination is as informative as the conventional SCC tests (See column 10, lines 36-52 and Table VI). The teachings of Alatossava as set forth above satisfy the limitations recited in claims 2-3.

Alatossava et al. also disclose a test kit which includes the elements as needed (see column 3, lines 48-63). This satisfies the limitations regarding the compositions and kits of claims 12-23.

Alatossava et al. do not explicitly disclose “contacting said crude milk sample with a fluorescent label”.

Alatossava et al. disclose that a PCR reaction was carried out with a lysed cell mixture instead of using purified DNA (see column 10, lines 40-43). As indicated in the specification, the

milk was diluted with EDTA, and then Tween 20 was added and the mixture was vortexed. All of the final solution was contacted with PicoGreen (see pg. 5, [0068] of the specification) in which the PicoGreen was used as a fluorescent dsDNA marker (see pg. 5, [0027]). Alatosava et al. further disclose that the presence of the target sequences can be determined by hybridization of a probe (See column 4, lines 43-60). The amount of dsDNA is measured fluorometrically with a specific dsDNA stain (see column 7, lines 3-7).

Alatosava et al. do not explicitly disclose using a fluorescent labeled DNA probe for target nucleic acid detection.

Since primers and probes are both oligonucleotides and they have specificity to a target nucleic acid sequence, one of ordinary skill in the art would have been motivated to apply the method of Alatosava et al. to detect a DNA in a crude milk sample with a reasonable expectation of success because the method of Alatosava et al. is to shorten the time needed for a proper mastitis diagnosis (see column 3, lines 31-32). It would have been prima facie obvious to carry out the method of detecting a DNA in crude milk as claimed.

### Summary

6. No claims are allowed.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/  
Primary Examiner, Art Unit 1637

Joyce Tung  
December 10, 2008